

TennCare Pharmacy Manual

(updated May 2003)

This Pharmacy Manual is designed to provide participating pharmacies with information regarding coverage and billing procedures for the TennCare Pharmacy Program. This TennCare Pharmacy Program is open to any willing pharmacy providers who comply with all of the requirements contained in the TennCare Participating Pharmacy Provider Agreement and this TennCare Pharmacy Manual. The TennCare Pharmacy Program provides pharmaceutical services to eligible TennCare/Medicare members (dually eligible) and the behavioral health pharmacy services for all eligible TennCare members. This Pharmacy Manual is a part of the Participating Pharmacy Provider Agreement and all requirements contained herein must be complied with by all participating pharmacy providers.

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100. Pharmacy Defined

Pharmacies licensed in Tennessee by the Tennessee Pharmacy Board, and all pharmacies outside Tennessee which are licensed under the laws of their respective states or when appropriate, also licensed in Tennessee, are eligible to participate in the TennCare program. The pharmacy must agree in writing, by completing and signing the TennCare Participating Pharmacy Agreement, to provide services to eligible TennCare members in compliance with all published state and federal regulations, all applicable state and federal laws, the agreement, TennCare policies and this Pharmacy Manual.

The pharmacy agrees to accept the payment authorized under the TennCare program for dispensing drugs when prescribed by a licensed prescriber acting under the authority granted by such licensure, and to bill the prescription in accordance with TennCare guidelines. As described in Section 3.3 of the TennCare Participating Pharmacy Agreement, payment to pharmacy providers authorized under the TennCare pharmacy program is payment in full.

101. Covered Services

101.1 Negative Drug Formulary List

Reimbursement for pharmacy services is limited to only those drugs covered by the TennCare Pharmacy Program for the TennCare/Medicare (dually eligible) members and all TennCare behavioral health pharmacy services for all eligible TennCare members. This TennCare program may utilize a negative drug formulary list or a preferred drug list (PDL). Any changes to a negative drug formulary list or preferred drug list will not take place until thirty (30) days after all affected providers are notified. A maintenance drug list and any over-the-counter (OTC) drugs covered by this program will be listed in a separate formulary. The negative drug formulary list or PDL, the maintenance drug list and the OTC list will be posted on the TennCare website (www.tennessee.gov/tenncare). Coverage and reimbursement for legend, maintenance and OTC drugs by the TennCare program is contingent upon a prescription written by a licensed prescriber. OTC drugs that are required to be floor stock items in a long term care facility will not be covered for members who are nursing home residents.

101.2 Maximum Days Supply/Refills

A maximum of 31 days supply and five refills within six months from the date of service on the original claim will be allowed for all covered drugs if authorized by a prescribing practitioner. Refills are covered only when filled according to the regulations, rules and laws set by the Tennessee Board of Pharmacy. The online, point-of-sale (POS) pharmacy claims processing system will deny any refills (or new prescriptions for the same drug) if submitted before a time period whereby 75% of the original days supply could be consumed by the member. TennCare publishes a list of maintenance drugs which may be filled for three month supplies or 100 units, whichever is greater. This maintenance list is posted on the TennCare website (www.tennessee.gov/tenncare).

101.3 DESI Drugs

Before enactment of the Federal Food, Drug and Cosmetic Act of 1938, drugs could be marketed in the United States as long as a drug's label did not present false information regarding the drug's strength and purity. The Federal Food, Drug and Cosmetic Act first established the requirement that a manufacturer has to prove the

safety of a drug before the manufacturer could market it in the United States.

In accordance with that statute, drugs marketed before the passage of the Federal Food, Drug and Cosmetic Act were "grandfathered" so that manufacturers, if they do not change the representations on the drugs' labels, were allowed to continue to market them unless evidence was developed to indicate that they were not safe (referred to as pre-38 drugs). However, once a manufacturer changed the representation on a pre-38 drug's label, that drug was considered by the FDA to be a "new drug" and the manufacturer was required to prove that the drug was safe for its intended use.

In 1962, the Federal Food, Drug and Cosmetic Act was amended to require that drugs sold in the United States be regulated more closely. Under the provisions of the Drug Amendments of 1962 (Public Law 87-781), all new drugs must be shown by adequate studies to be both safe and effective before they can be marketed. This legislation also applied retroactively to all drugs approved as safe from 1938 to 1962 (referred to as pre-62 drugs). These pre-62 drugs were permitted to remain on the market while evidence of their effectiveness was reviewed. The program established under which the FDA would review the effectiveness of drugs approved between 1938 and 1962 was named the Drug Efficacy Study Implementation (DESI) program.

If the DESI review indicates a lack of substantial evidence of a drug's effectiveness for all of its labeled indications, the FDA will publish a Notice of Opportunity for a hearing (NOOH) in the Federal Register concerning its proposal to withdraw approval of the drug for marketing. At that time, a manufacturer of that drug or identical, related or similar (IRS) drugs has the opportunity to request a hearing and provide FDA with documentation of the effectiveness of the drug product before a final determination is made. Drugs for which a NOOH has been published are referred to as less-than-effective (LTE) drugs. The IRS counterpart of a LTE drug is also considered as LTE.

In accordance with Section 1903(i)(5) of the Social Security Act, federal funds participation (FFP) is not available for LTE/IRS drugs for which a NOOH is issued for all labeled indications. This means that TennCare will not pay for LTE/IRS drugs. A list of the DESI drugs may be found at the following web addresses: <http://cms.hhs.gov/medicaid/drugs/desi.pdf> or www.tennessee.gov/tenncare.

101.4 Prior Approval for Non-Covered Drugs

Drugs and therapeutic categories listed in the Negative Drug Formulary List or drugs not listed on the PDL, may be requested through the prior approval process. It is important to remember that some drugs or categories of drugs, such as DESI, LTE and IRS, are cannot be reimbursed by Medicaid or TennCare. SEC. 1927. [42 U.S.C. 1396r-8] states:

The following drugs or classes of drugs, or their medical uses, may be excluded from coverage or otherwise restricted:

- (A) Agents when used for anorexia, weight loss, or weight gain.*
- (B) Agents when used to promote fertility.*
- (C) Agents when used for cosmetic purposes or hair growth.*
- (D) Agents when used for the symptomatic relief of cough and colds.*
- (E) Agents when used to promote smoking cessation.*
- (F) Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.*
- (G) Nonprescription drugs.*

A prescriber may request prior approval for drugs listed on the Negative Drug Formulary List or not listed on the PDL by:

Calling----- 1-888- 816-1680 toll free

Faxing-----1-888-298-4130 toll free or in the Nashville area 615-253-5481

Or writing to: Bureau of TennCare
Attn: TennCare Pharmacy Program
729 Church Street
Nashville, Tennessee 37247-6501

102. Long Term Care Pharmacy Services

102.1 Long Term Care Pharmacy Provider Requirements

All long term care (nursing home) pharmacy providers must bill the TennCare Pharmacy Program only for those drugs consumed by the eligible TennCare member. Long term care pharmacy providers will be eligible to receive a \$5.00 dispensing fee when a 28-day supply of a covered medication is dispensed in accordance with all applicable TennCare rules and regulations to TennCare/Medicare, eligible TennCare members who are residents of a nursing home. Covered medications dispensed in quantities less than 28-day supplies will be reimbursed with a \$2.50 dispensing fee.

All pharmacists involved in the dispensing of covered medications to TennCare/Medicare, eligible nursing home residents must comply with all of the following requirements in order to be a TennCare participating long term care pharmacy provider:

- ✍ Maintain appropriate patient profiles that are reviewed and updated before dispensing occurs.
- ✍ Dispense a maximum of a seven (7) days supply at a time.
- ✍ Develop and follow a procedure manual that includes stop-order policies and procedures as well as the process to follow to assure TennCare is only billed for drugs actually consumed by the patient.
- ✍ Conduct (and document) in-service training for nursing home staff at least quarterly.
- ✍ Complete 15 hours of A.C.P.E. approved continuing education annually that are directly related to the care of a nursing home resident.
- ✍ Bill TennCare only for medications actually consumed by the patient.
- ✍ All solid oral dosage forms of covered medication must be provided to the long term care facility in unit dose packaging.
- ✍ Long term care pharmacy providers must never bill TennCare for the medications of TennCare/Medicare members who are skilled nursing patients in a long term care facility and their drugs are covered by Medicare under a PPS for the nursing home.

102.2 Unit Dose Packaging

A unit dose is defined as a sealed container packaged by a FDA-approved drug manufacturer or repackager. This unit of use medication bears the name and strength of the drug, expiration date, control/lot number, and

the name and address of the manufacturer. The use of unit dose packaging is required to allow for the return to stock of drugs not consumed by the patient, as allowed by state and federal laws and regulations.

102.3 Billing Dates

Any long term care pharmacy claims submitted that are not for pharmacy services actually rendered during the month of the billing invoice/claim are in violation of the TennCare Participating Pharmacy Provider Agreement. The date of service for medications supplied to an eligible, TennCare/Medicare nursing home resident by a long term care pharmacy provider should be the last date of the month in which the medication was taken.

103 Pharmacy Audits

The TennCare Bureau and the Division of Audit, Office of the Comptroller are responsible for post payment audits of participating pharmacies in the TennCare Program. TennCare rules and federal law require that auditable records be maintained on the premises of the dispensing pharmacy for inspection purposes for a minimum of five (5) years.

Auditable records include:

1. All drug invoices, both wholesale and direct
2. Usual and customary fee schedules
3. Competitive price files
4. Prescriptions/nursing home orders
5. Patient signature logs that verify prescriptions for TennCare members were received and all appropriate patient counseling laws and rules were complied with (in the ambulatory setting)
6. Long term care pharmacy procedure manuals that include stop-order policies and procedures as well as the process to follow to assure TennCare is only billed for drugs actually consumed by the long term care patient

The purpose of the TennCare pharmacy audit is to verify at least the following: (1) that the information submitted to TennCare on pharmacy claims for reimbursement is documented by the prescriptions; (2) that an accurate estimated acquisition cost was used; (3) that the billed amount including the dispensing fee does not exceed the usual charge to the general public, and (4) that all of the requirements of the TennCare Participating Pharmacy Provider Agreement and the TennCare Pharmacy Manual are complied with.

All participating pharmacies are subject to routine audits. The pharmacy provider may or may not be contacted by the TennCare Bureau or the Comptroller's Office prior to the audit. It is the pharmacy provider's responsibility to see that all requested material is on hand upon the arrival of any auditors. If prescription and refill information is computerized, the pharmacy provider must be prepared to devote the time necessary to display the on-line information to the auditor or provide daily printouts with appropriate information. However, the auditor may want to review hardcopies of prescriptions in order to perform any necessary audit functions and the pharmacy provider will provide those hardcopies when asked.

Upon arrival at the pharmacy, the auditor will request to see the owner or manager and will present identification. The owner/manager should determine a work place that would be most convenient. The records, purchase invoices and/or prescription files are then provided to the auditor. The auditor will interview the owner/manager briefly to obtain information for completion of the required TennCare Pharmacy Audit forms. Before leaving, the auditor will discuss any major billing problems identified in the prescription

review and will explain the manner in which the results of the audit will be reported.

Upon return to the office, all reports will be completed by the auditor. When all data have been compiled, if a violation of the TennCare Participating Pharmacy Provider Agreement, the TennCare Pharmacy Manual or any applicable state or federal laws or regulations is found during the review, a letter will be sent to the pharmacy provider explaining any corrective actions that need to be taken or any sanctions that may be placed on the pharmacy. If corrective actions are needed, the pharmacy will respond within ten (10) days, in writing, to the TennCare Bureau in order to explain the exact corrective actions taken and to provide assurances that the cited violations will not recur. TennCare reserves the right to contract with outside vendors for audit performance

104 Signature Logs

Every participating outpatient pharmacy provider must keep a patient signature log to document that the prescriptions were received by the TennCare member or his/her responsible agent and that the appropriate patient counseling was offered as required by state and federal law.

105 Patient Profiles

Every participating pharmacy provider must keep patient profiles for TennCare members as required by state and federal law.

106 Prospective Drug Utilization Review (Pro-DUR)

Every participating outpatient pharmacy provider must perform Pro-DUR for TennCare members as required by state and federal law.

107 Patient Counseling

Every participating outpatient pharmacy provider must provide patient counseling for TennCare members as required by state and federal law.

108 Posting Information for TennCare Members

Every participating outpatient pharmacy provider will be required to post information regarding TennCare members' appeal rights in a conspicuous place near the pharmacy counter.

109 Grier Consent Decree

Every participating pharmacy provider is required to comply fully with all aspects of the final *Grier* Consent Decree, which details a TennCare member's appeal rights and the responsibilities of a participating pharmacy provider to provide emergency supplies of medications when appropriate.

When a TennCare patient enters a pharmacy with a prescription for a non-formulary drug (which is not a DESI, LTE, or IRS drug and is included in one of the therapeutic categories required to be covered by TennCare and is not included in a therapeutic category previously not covered by Tennessee Medicaid, such as fertility drugs, acne preparations, over-the-counter drugs/products or cough and cold preparations), the pharmacist is required to do the following:

- (a) Contact the prescriber and inform him/her of the alternative(s) available on the TennCare drug formulary and get a new oral prescription, OR
- (b) When the prescriber indicates that the alternatives have either been tried and failed or are contraindicated for some reason, assist the prescriber in requesting prior approval from the TennCare Prior Approval Unit, OR
- (c) Contact TennCare or the claims processor to request a POS override for a 14-day emergency supply for dispensing, when the prescriber or TennCare are unavailable.

In short, the patient should not leave the pharmacy without the original prescription medicine, a 14-day supply of the medication or an alternative approved by the prescriber.

A pharmacist's professional judgment, when dealing with emergency situations or abusive drugs, is not to be encumbered by the emergency supply requirement. Prescriptions are requests that should be honored in most instances by the pharmacist, but decisions about cases of fraud, abuse, misuse, inappropriate use, drug interactions, therapeutic duplication, drug-disease contraindications, or non-covered medications (such as DESI drugs) should rightfully be decided by the dispensing pharmacist.

NOTE: DESI, LTE, and IRS drugs were not covered under the Tennessee Medicaid drug program, prior to TennCare, as federal financial participation was not available for these drugs under Medicaid. Many of the cough and cold preparations are considered to be in the DESI category and therefore should not be covered by this pharmacy program. Drugs that were excluded under the Tennessee Medicaid program (and OBRA 1990) that preceded the implementation of TennCare, such as acne preparations or fertility drugs, are not included in the list of mandatory therapeutic categories that must be covered by the TennCare Pharmacy Program. Accordingly, these drugs are not considered to be emergency medications that would be covered under the requirements of any emergency supply provisions.

Ongoing outpatient pharmacy services:

Notice of termination or suspension of ongoing outpatient TennCare authorized pharmacy services is provided by the pharmacist at the time the prescription for outpatient pharmacy is presented. If TennCare is unable to respond to a prior approval request on the day of the request or if the prescriber is unavailable, TennCare must provide a 14-day supply of the prescribed medication, provided that: (1) the medication is not classified by the FDA as Less Than Effective (i.e., a DESI, LTE, or IRS drug); or (2) the medication is not a drug in a non-covered TennCare therapeutic category (e.g., appetite suppressants, drugs to treat infertility); or (3) use of the medication is not contraindicated because of the patient's medical condition or possible adverse drug interaction. With regard to non-formulary medications, if TennCare is able to respond to a request for prior approval to continue the ongoing pharmacy services on the day the request is made, and the prescriber attests there is no formulary medication that is therapeutically equivalent and clinically efficacious, TennCare must continue to provide the prescribed medication pending the conclusion of an

appeal to the TennCare Bureau. Notice of appeal rights and the opportunity to request continuation of services will be provided by the pharmacy (TennCare Drug Store Notice).

Initial requests for outpatient pharmacy services:

If TennCare is unable to respond to a prior approval request on the day of the request or if the prescriber is unavailable, TennCare must provide a 14-day supply of the prescribed medication, provided that: (1) the medication is not classified by the FDA as Less Than Effective (i.e., a DESI, LTE, or IRS drug); or (2) the medication is not a drug in a non-covered TennCare therapeutic category (e.g., appetite suppressants, drugs to treat infertility); or (3) use of the medication is not contraindicated because of the patient's medical condition or possible adverse drug interaction; or (4) (as the patient is not already taking the medication) use of the medication for a 14-day period possibly followed by abrupt discontinuance of the drug would be medically contraindicated. Notice of appeal rights will be provided by the pharmacy.

The entire, revised *Grier* Consent Decree is posted on the TennCare website at: www.tennessee.gov/tenncare .

110 Drug Rebates

Under the provisions of OBRA 1990, TennCare will bill pharmaceutical manufacturers for rebates each quarter. In the event that any rebates are disputed by the manufacturers because a TennCare participating pharmacy billed TennCare using an inaccurate NDC (national drug code) number, those claims will be voided and all reimbursement recouped. Continued use of invalid NDCs by participating pharmacies may result in termination of their TennCare Participating Pharmacy Provider Agreement and removal from the TennCare program. The TennCare Pharmacy Program can only cover those drugs, including those covered OTC products, for which rebates are available, that is, drugs manufactured or distributed by entities that have signed a rebate agreement with the federal government (HCFA).

111 Copays, Coinsurance and Deductibles

Every participating pharmacy provider is required to collect all applicable copays, coinsurance and deductibles for prescription medications from TennCare members. The TennCare POS pharmacy claims processing system will inform pharmacies of all applicable copays, coinsurance and deductibles.

112 Payment in Full

Acceptance of TennCare reimbursement for pharmaceutical services provided to TennCare members shall be considered payment in full. Participating pharmacy providers may not bill TennCare members for any covered services. Pharmacies may not make additional charges to TennCare members for services reimbursable under the TennCare Pharmacy Program.

113 Medicare Coverage of Medications

All medications prescribed for TennCare/Medicare (dually eligible) members that are covered by Medicare, must be billed to Medicare. Failure to do so may result in a voided pharmacy claim and recoupment.

114 Pharmacy Law

If a participating pharmacy provider is convicted of any violation of state or federal pharmacy law or regulations, that pharmacy may be excluded from the TennCare Program. Participating pharmacies are required to comply with all state and federal pharmacy laws and regulations.

115 Prescriber Codes

After July 1, 2002 pharmacies will identify the prescriber on all pharmacy claims for TennCare members covered by the TennCare Pharmacy Program by using the appropriate DEA number. Failure to use the correct DEA number to identify the prescriber accurately may result in a denied claim.

116 Pharmacy Billing Numbers

Pharmacies will identify the dispensing pharmacy on all pharmacy claims for TennCare members covered by the TennCare Pharmacy Program by using their NCPDP number, formerly known as their NABP Number (National Association of Boards of Pharmacy).

117 Billing Instructions

Complete billing instructions for the transmission of pharmacy claims for TennCare members covered by the TennCare Pharmacy program will be furnished to pharmacies by the TennCare Bureau and the POS pharmacy claims processor under contract to TennCare. Assistance for all pharmacy billing questions or problems may be attained by calling 1-888-816-1680.